DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Mr. Robert F. Sullivan
Senior Director
FDA Regulatory Affairs
STERIS Corporation
5960 Heisley Road
Mentor, Ohio 44060

JAN 1 0 2017

Re: K092823
Trade/Device Name: Amsco Warming Cabinet
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: Class II
Product Code: LGZ
Dated: September 11, 2009
Received: September 14, 2009

Dear Mr. Sullivan:

This letter corrects our substantially equivalent letter of December 18, 2009.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith -S

Erin I. Keith, M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Amsco Warming Cabinet

Indications For Use:

The Amsco Warming Cabinet is designed to raise the temperature of blankets, linens and sterile surgical irrigation solutions and IV solutions to an acceptable level for various surgical, obstetrical, emergency, critical care and other healthcare applications

Prescription Use _____ AND/OR Over-The-Counter Use ____X___
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

for CR

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K042823

K092803

STERIS®

DEC 18 2009

510(k) Summary
For
Amsco Warming Cabinet

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Contact: Robert F. Sullivan
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Summary Date: September 11, 2009

1. Device Name

Trade Name:	Amsco Warming Cabinet
Common/usual Name:	Warming Cabinet
Classification Name:	Warmer, Irrigation Solution Warmer, Cabinet

2. Predicate Device

STERIS Amsco Warming Cabinet (Pre-Amendment)
Enthermics EC-7701 Fluid Warming Cabinet, K993797, January 20, 2000

3. Description of Device

The Amsco Warming Cabinet is designed to store and warm sterile IV solutions, surgical irrigation solutions, linens and/or blankets to an acceptable level for hospital and surgical outpatient center applications.

The upper compartment of the 18" (457mm) deep model holds up to 24(1-liter) liquid bags or bottles and 14 (1-liter) IV solution bags; the lower compartment holds up to 72 (1-liter) liquid bags or bottles.

The upper compartment of the 24" (610mm) deep model holds up to 30 (1-liter) surgical flasks; the lower compartment holds up to 90 (1-liter) surgical flasks.

4. Intended Use

The Amsco Warming Cabinet is designed to raise the temperature of blankets, linens and sterile surgical irrigation solutions and IV solutions to an acceptable level for various surgical, obstetrical, emergency, critical care and other healthcare applications.

5. Description of Safety and Substantial Equivalence

The Amsco Warming Cabinet is nearly identical to the two predicate devices in all material respects. A table comparing the technological characteristics of the proposed Amsco Warming Cabinet to the predicates is provided in Table 5-1.

Table 5-1 Summary of the Proposed Device and Predicate Devices
Technological Characteristics

Features	Amsco Warming Cabinet (IV Solution Capability)	Amsco Warming Cabinet (Pre-amendment)	EC-7701 Fluid Warming Cabinet (K993797)
Intended Use	The Amsco Warming Cabinet is designed to raise the temperature of blankets, linens and sterile surgical irrigation solutions and IV solutions to an acceptable level for various surgical, obstetrical, emergency, critical care and other healthcare applications. The Amsco Warming Cabinet is designed to hold a combination of flasks and/or dry goods.	Amsco Warming Cabinet is for heating flasked solutions, blankets and similar clinical articles.	The Enthermics Medical Systems EC-7701 Fluid Warming Cabinet is designed to safely store and warm irrigation fluids or injection fluids in accordance with the recommended warming temperatures and storage times stated in the fluid manufacturer's labeling.
Heating System	Electric heater and fan blower (Convection heating)	Steam heat or Electric heater blanket and fan blower (Convection heating)	Fully insulated electrothermal cable array (Convection heating)
Unit Configuration	Single/Double	Single/Dual	Single
Unit Depth	18" or 24"	18" or 24"	
Model	Wall or Counter	Wall or Counter	Wall
Interior and Exterior Surfaces	Stainless Steel, ABS Plastic and laminated galvanized steel	Stainless Steel	Stainless Steel
Installation	Free-Standing (mobile) or Recessed	Open-Mounted or Recessed	Free-standing (mobile) or Recessed
Door	Stainless Steel (Solid and Glass)	Stainless Steel	Stainless Steel (Glass)
Cabinet Storage Capacity	18" upper / single chamber - 3.2 cu ft – up to 24 (1-liter) bottles 18" lower chamber - 8.5 cu ft – up to 72 (1-liter) bottles 24" upper / single chamber - 4.3 cu ft – up to 30 (1-liter) bottles 24" lower chamber - 11.6 cu ft – up to 90 (1-liter) bottles	Dual Compartment Model - Two shelves 15 flasks – 18" upper 45 flasks – 18" lower 20 flasks – 24" upper 60 flasks – 24" lower Single Compartment Model – One shelf 15 flasks – 18" 20 flasks – 24"	The cabinet is equipped with three (3) white, epoxy-coated wire baskets, each with a 24 liter capacity.

Features	Amsco Warming Cabinet (IV Solution Capability)	Amsco Warming Cabinet (Pre-amendment)	EC-7701 Fluid Warming Cabinet (K993797)
Cabinet Volume	18" upper chamber – 3.1 cu ft 24" upper chamber – 4.2 cu ft 18" lower chamber – 8.9 cu ft 24" lower chamber – 12 cu ft	18" upper chamber – 3.1 cu ft 24" upper chamber – 4.2 cu ft 18" lower chamber – 8.9 cu ft 24" lower chamber – 12 cu ft	
Controls	Digital Push Button keypad / power switch / Digital LCD temperature display / mode selection buttons / door ajar indicator / Over-temperature light for each compartment / Data port for retrieval of stored temperatures.	Thermostat / power switch / fuse with indicating light / color coded temperature selector	Electronic control consists of 4 digit LED display, on/off key, increase and decrease keys, integrated lock feature and a series of prompt sequence indicators.
Software	Unit contains software	Not Applicable	Not applicable
Temperature Selection Range	90°F (32°C) to 160°F (71°C)	95°F to 150°F (35°C to 65°C)	90°F (32°C) to 150°F (66°C)
Temperature Lock	Temperature lock-out function to prevent unauthorized temperature changes.	Not Available	The device allows the user to "lock" the mode (IRR or INJ) and temperature setting controls.
Door Lock	All configurations will be equipped with either a manual mechanical door lock or optional electronic door lock system for each compartment	Available by SSQ (Special Sales Quote) only	Available as an option
Over Temperature Alarm Point	Visual and audible alarm if unit has a chamber temperature greater than 10°F (5.5°C) above set temperature. In the event of an over temp condition, sensors automatically turns off the heater(s).	Visual alarm if unit has a chamber temperature greater than 12°F above set temperature. In the event of an over temp condition, sensors automatically turns off the heater(s).	Visual and audible alarm if unit has a chamber temperature greater than 10°F (5.5°C) above set temperature. In the event of an over temp condition, the heating system shuts down.
Voltage Requirements	110/120 Vac, 220/240 Vac nominal, 50/60 HZ	Electric Model: 110/120 Vac, 220/240 Vac nominal, 50/60 HZ Steam Model: 120 VAC single phase	125 Vac, 60 HZ, 1 ph